

IN THE COURT OF APPEALS OF TENNESSEE
AT KNOXVILLE
October 25, 2007 Session

REBECCA LYNN SPARKS v. MICHAEL C. MENA, ET AL.

**Appeal from the Circuit Court for Hamilton County
No. 02C437 L. Marie Williams, Judge**

No. E2006-02473-COA-R3-CV - FILED FEBRUARY 6, 2008

The plaintiff brought this action alleging that a surgical device manufactured by the defendant was in a defective and unreasonably dangerous condition, which resulted in the accidental laceration of her aorta during abdominal surgery. Upon our determination that the trial court erred in excluding evidence of other similar incidents involving actual or potential surgical injuries with the same model of device, and that the trial court erred in excluding the testimony of plaintiff's expert witness, we vacate the judgment of the trial court and remand the case for a new trial.

**Tenn. R. App. P. 3 Appeal as of Right; Judgment of the Circuit Court Vacated;
Case Remanded**

SHARON G. LEE, J., delivered the opinion of the court, in which HERSCHEL P. FRANKS, P.J., and CHARLES D. SUSANO, JR., J., joined.

G. Brent Burks, Chattanooga, Tennessee, for the Appellant, Rebecca Lynn Sparks.

Douglas M. Campbell, Chattanooga, Tennessee, for the Appellee, Ethicon Endo-Surgery, Inc.

OPINION

I. Background

Rebecca Lynn Sparks was injured during surgery to remove her gallbladder when a trocar, a surgical device manufactured by the defendant Ethicon Endo-Surgery, Inc., ("Ethicon") accidentally lacerated her aorta. Ms. Sparks sued the surgeon, Dr. Michael Mena; the hospital, Erlanger Medical Center; and Ethicon. The trial court granted Dr. Mena and Erlanger Medical Center summary judgment, and Ms. Sparks has not appealed this decision. The product liability case against Ethicon

alleging that the trocar was defective and unreasonably dangerous was tried before a jury, which returned a verdict in Ethicon's favor.

II. Issues

Ms. Sparks appeals, raising several issues, of which we find the following two to be determinative:

1. Whether the trial court erred in excluding evidence of prior similar incidents involving the same model of trocar as injured Ms. Sparks.

2. Whether the trial court erred in excluding the expert testimony of Ted Eyrick, Ph.D., a mechanical engineer who proffered his testimony that, among other things, the trocar was likely defective and unreasonably dangerous when it left Ethicon's control.

III. Analysis

A. Standard of Review

Both of the issues we address involve the propriety of the trial court's determination of the admissibility of evidence at trial. Issues regarding whether a trial court has correctly construed and applied the governing Tennessee Rules of Civil Procedure and Tennessee Rules of Evidence in making an admissibility determination address themselves to the trial court's discretion, and we review such issues under the "abuse of discretion" standard. *Hunter v. Ura*, 163 S.W.3d 686, 703 (Tenn. 2005); *DeLapp v. Pratt*, 152 S.W.3d 530, 538 (Tenn. Ct. App. 2004). "[T]rial courts are accorded a wide degree of latitude in their determination of whether to admit or exclude evidence, even if such evidence would be relevant." *Id*; *Dickey v. McCord*, 63 S.W.3d 714, 723 (Tenn. Ct. App. 2001). A trial court abuses its discretion only when it "applies an incorrect legal standard, or reaches a decision which is against logic or reasoning that causes an injustice to the party complaining." *Eldridge v. Eldridge*, 42 S.W.3d 82, 85 (Tenn. 2001).

B. Admissibility of Other Similar Incidents

The surgical instrument that lacerated Ms. Sparks's aorta, an Endopath 512SD trocar, has a cutting blade that allows a surgeon to insert the trocar into a patient's abdomen, and a safety shield that is designed to quickly spring forward to cover the blade once the trocar enters the abdominal cavity so that the blade cuts nothing further. Ms. Sparks's theory at trial was that the trocar used in her surgery had a defect that prevented the safety shield from covering the blade after it entered her abdominal cavity, causing the laceration, resultant significant internal bleeding, and more extensive surgery. At trial, Ms. Sparks sought to introduce 21 Ethicon analysis reports documenting 23 claims of similar incidents involving 512SD trocars within the two years prior to her injury. Because the trial court utilized an incorrect legal standard in determining the admissibility of the evidence of similar incidents, we find merit in Ms. Sparks' argument that the trial court erred in excluding all but two of the reports.

Ms. Sparks made an extensive offer of proof regarding the analysis reports, which documented the nature of the claims that the 512SD trocars were defective or nonfunctional, whether the patient had been injured, Ethicon's analysis of the returned trocar, and its conclusions. At the conclusion of the offer of proof, the trial court specifically found that Tenn. R. Evid. 404(b) was applicable, and followed Rule 404(b)'s requirements for admissibility, which provide as follows:

(b) Other Crimes, Wrongs, or Acts. Evidence of other crimes, wrongs, or acts is not admissible to prove the character *of a person* in order to show action in conformity with the character trait. It may, however, be admissible for other purposes. The conditions which must be satisfied before allowing such evidence are:

- (1) The court upon request must hold a hearing outside the jury's presence;
- (2) The court must determine that a material issue exists other than conduct conforming with a character trait and must upon request state on the record the material issue, the ruling, and the reasons for admitting the evidence;
- (3) The *court must find proof of the other crime, wrong, or act to be clear and convincing*; and
- (4) The court must exclude the evidence if its probative value is outweighed by the danger of unfair prejudice.

Tenn. R. Evid. 404(b) (emphasis added).

The language of the first sentence of the above rule makes it clear that Rule 404(b) applies only to evidence of other acts of a person, not to "character" evidence of an inanimate object. The 2005 Advisory Commission Comment to the rule states that "[t]he word 'person' in Rule 404(b) has been construed to refer *solely* to the defendant in a criminal prosecution" (emphasis added; citing *State v. Stephens*, 78 S.W.3d 817 (Tenn. 2002)). The parties have cited no judicial opinion, nor has our research revealed one, where Tenn. R. Evid. 404(b) was applied to evidence of "other acts" of an allegedly defective product. The court in *Copley v. Davis*, No. 86-362-II, 1987 WL 9161, at *2 (Tenn. Ct. App. M.S., filed Apr. 10, 1987) noted this distinction in stating, "[o]ther incidents are admissible to show the propensity or probability of an incident involving inanimate objects or animals; but the rule is otherwise as to proof of other wrongful acts or negligence of a person." The trial court, citing Rule 404(b)(3), ruled that "the Court must determine that the proof of the other acts offered into evidence must be clear and convincing," and allowed only two of the reports of prior similar incidents into evidence.

Recently, this court, presented with a similar question of admissibility of other similar incidents in a products liability case, restated the law and outlined the pertinent authorities in Tennessee on this issue as follows:

Admissibility of evidence of other accidents is a common issue arising in negligence and products liability cases. 1 MCCORMICK ON EVIDENCE § 200, at 800 (Kenneth S. Broun ed., 6th Practitioner's Ed. 2006). In Tennessee, "evidence of other accidents is admissible at trial for two purposes: (1) to show the existence of a particular dangerous condition or (2) to show the defendant's knowledge of the dangerous condition." *Stroming v. Houston's Restaurant, Inc.*, No. 01A-01-9304-CV-00189, 1994 WL 658542, at *2 (Tenn. Ct. App. Nov. 23, 1994) (citing *John Gerber Co. v. Smith*, 150 Tenn. 255, 266, 263 S.W. 974, 977 (1924); *Winfree v. Coca-Cola Bottling Works*, 19 Tenn. App. 144, 147, 83 S.W.2d 903, 905 (1935); *Ellis v. Memphis Cotton Oil Co.*, 3 Tenn. Civ. App. (Higgins) 642, 650 (1913)). Cases in Tennessee have also held that accidents occurring after the one in question may be admissible to show the dangerous nature of the product in question:

Where the dangerousness or safe character of the place, method, or appliance which is alleged to have caused the accident or injury is in issue, evidence is admissible in a proper case that other similar accidents or injuries, actual or potential, have *therefore, or at the same time, or thereafter* resulted at or from such place, method, or appliance.

Winfree, 19 Tenn. App. at 147, 83 S.W.2d at 905 (emphasis added), Petition for Certiorari Denied by Supreme Court, June 10, 1935; *see also Graham v. Cloar*, 30 Tenn.App. 306, 205 S.W.2d 764 (Tenn. Ct. App. 1947), Petition for Certiorari Denied by Supreme Court October 3, 1947. "If the evidence is being offered to show the existence of a particular hazard or danger, the party seeking to use the evidence must lay a foundation establishing substantial similarity between the prior accidents and the present accident." *Stroming*, 1994 WL 658542, at *2 (citing *John Gerber Co. v. Smith*, 150 Tenn. at 266, 263 S.W. at 977). The similarity requirement does not require that the circumstances of the accidents be identical in every particular. *Id.* at *3, 263 S.W. 974 (citing 1 MCCORMICK ON EVIDENCE § 200, at 844 n. 4 (John W. Strong ed., 4th Practitioner's Ed. 1992)).

Flax v. DaimlerChrysler Corp., No. M2005-01768-COA-R3-CV, 2006 WL 3813655, at *17 (Tenn. Ct. App. W.S., filed Dec. 27, 2006), *perm. app. granted* (Tenn. May 14, 2007) (emphasis in original). The *Flax* court upheld the admission of evidence regarding 37 other similar incidents in a products liability action involving the collapse of a vehicular seat back. *Id.* at *18. The rule in Tennessee as restated above is in accordance with the general rule followed in other jurisdictions.¹

Of the 21 analysis reports offered by Ms. Sparks, 18 meet the substantial similarity requirement. All of the reports document complaints about the same make and model of trocar, the 512SD. By way of example, the documents contain reports of such instances as: “the 512SD safety shield would not cover the knife after passing through the abdominal wall;” “the shield did not come back over the blade when the trocar was inserted, and a vein was punctured;” “another 512SD blade shield failed to advance after entering the abdomen;” “the 512SD instrument safety shield did not close back over the blade after having reached the abdominal cavity;” and “the surgeon and the nurse checked the instrument and could not activate the safety shield (it would not return into the safety lock position).” These analysis reports contain descriptions of incidents substantially similar to what Ms. Sparks alleges occurred in her case, causing her injury.

In each instance documented by the analysis reports, the allegedly defective trocar was returned to Ethicon for analysis. In all but two of the cases, Ethicon’s examiners reported that they found nothing wrong with the returned trocar. The trial court allowed the introduction of only the two reports where Ethicon reported finding that the trocar did not function correctly, or that it was able to re-create the alleged problem during testing. We are of the opinion that the fact that Ethicon reported finding no defect in its own returned product upon inspection pertains to the weight to be afforded the evidence, and not its admissibility. In other words, Ethicon is free to argue to the trier of fact that no weight should be given to the allegations of the analysis reports regarding other similar incidents because Ethicon reported finding nothing wrong with the product, but that fact does not render the evidence inadmissible. The trial court’s application of the legal standard provided by Tenn. R. Evid. 404(b) to the evidence of other similar incidents was reversible error in this case. On remand, those 18 reports² documenting claims of instances where the safety shield of the trocar would not retract, or the knife blade remained exposed inside the patient’s abdominal cavity, are

¹For a collection of case citations to decisions in other jurisdictions on this issue following the general principle that “in an action where the plaintiff seeks to charge the defendant with liability for damage or injury due to defects in an appliance, mechanical device, or other product belonging to, under the control of, or manufactured by the defendant, evidence of other accidents involving the same product is generally admissible to show its dangerous or hazardous nature, if the accidents occurred under the same or substantially similar conditions as that involving the plaintiff, and with reasonable proximity in time,” see Ferdinand S. Tinio, Annotation, *Products Liability: Admissibility of Evidence of Other Accidents to Prove Hazardous Nature of Product*, 42 A.L.R.3d 780 (1972).

²The analysis reports deemed admissible are those dated as follows: 4/19/99, 5/18/99, 9/23/99, 9/24/99, 9/30/99 (reporting two instances; both trocars), 12/10/99, 10/18/99, 11/23/99, 3/6/00, 3/7/00, 3/10/00, 3/13/00, 3/16/00, 3/23/00, 5/24/00, 6/12/00, 9/26/00, and 11/27/00.

admissible for two purposes: “(1) to show the existence of a particular dangerous condition or (2) to show the defendant’s knowledge of the dangerous condition.” **Flax**, 2006 WL 3813655, at *17; **Winfree v. Coca-Cola Bottling Works**, 83 S.W.2d 903, 905 (Tenn. Ct. App. 1935).

C. Admissibility of Expert Testimony

Ms. Sparks also takes issue with the trial court’s decision to exclude the expert testimony of Dr. Ted Eyrick, a professional mechanical engineer who proffered his opinion that, among other things, the trocar was likely defectively manufactured and in an unreasonably dangerous condition when it left Ethicon’s custody and control, and that “more likely than not, the knife collar on the Sparks trocar became bent in a downward position, which allowed the Sparks trocar to arm properly, but prevented the safety shield from springing back to cover the knife blade after the trocar was inserted into Plaintiff’s insufflated abdomen.” The trial court held that Dr. Eyrick was unqualified to testify as an expert witness. We have determined that Dr. Eyrick possesses the education, training and experience that qualifies him to render an opinion on the mechanical design and operation of the device at issue, and consequently that the trial court erred in disqualifying him as an expert under Tenn. R. Evid. 702 and 703.

The admission of expert proof is governed by Tennessee Rules of Evidence 702 and 703. **State v. Copeland**, 226 S.W.3d 287, 301 (Tenn. 2007); **Brown v. Crown Equipment Corp.**, 181 S.W.3d 268, 273 (Tenn. 2005). Tennessee Rule of Evidence 702 provides that “[i]f scientific, technical, or other specialized knowledge will substantially assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise.” Tennessee Rule of Evidence 703 states that “[t]he facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing.”

In the case of **McDaniel v. CSX Transportation, Inc.**, 955 S.W.2d 257, 265 (Tenn. 1997), the Supreme Court set forth several nonexclusive factors a court could consider in determining the reliability of scientific testimony, including:

- (1) whether scientific evidence has been tested and the methodology with which it has been tested;
- (2) whether the evidence has been subjected to peer review or publication;
- (3) whether a potential rate of error is known;
- (4) whether . . . the evidence is generally accepted in the scientific community; and
- (5) whether the expert’s research in the field has been conducted independent of litigation.

Brown v. Crown Equipment Corp., 181 S.W.3d at 268, 274 (Tenn. 2005). In **Brown**, the Supreme Court reemphasized the non-exclusivity of the **McDaniel** factors and cautioned that “[t]hese factors

are not mandated in every case in which expert evidence is offered and should not be applied unless the factor or factors provide a reasonable measure of the expert's methodology.” *Id.* at 272. The *Brown* Court further noted that “[t]he rigid application of the *McDaniel* factors to all expert testimony is problematic because all expert testimony may not ‘fit’ within the factors.” *Id.* at 277.

The *Brown* Court identified two other nondefinitive factors that a trial court may consider in assessing the reliability of an expert’s methodology: (1) the expert’s qualifications for testifying on the subject at issue, and (2) the connection between the expert’s knowledge and the basis for the expert’s opinion. *Id.* at 274; *Johnson v. Hancock Funds*, 217 S.W.3d 414, 427 (Tenn. Ct. App. 2006). In the present case, we first examine Dr. Eyrick’s qualifications for testifying on the subject of the mechanics and operation of the trocar at issue. The *Brown* Court held as follows regarding the “qualifications” factor:

This factor is applicable particularly where the expert’s personal experience is essential to the methodology or analysis underlying his or her opinion. We, however, caution that using this factor as the sole basis of reliability would result in a reconsideration of the Rule 702 requirement that the expert witness be qualified by knowledge, skill, experience, training, or education to express an opinion within the limits of the expert’s expertise.

Brown, 181 S.W.3d at 274.

Dr. Eyrick holds a bachelor’s degree and a master’s degree in mechanical engineering, and in 1970 he earned his Ph.D. degree in mechanical engineering with a specialty in the biomedical field from Tufts University. Dr. Eyrick is licensed as a professional engineer by the state of Texas. Dr. Eyrick is the holder of seven United States patents and ten foreign patents, all of which involve medical devices. Dr. Eyrick testified that his prior work experience has involved the development and testing of medical devices, the manufacturing of medical devices (including quality control and analysis of allegedly defective products) and regulatory compliance issues. Since 1981, Dr. Eyrick has worked with EYTEK Consulting Company, providing consulting on design and safety reviews for medical devices, FDA regulatory compliance, litigation, and hospital risk reduction surveys. It is evident from the record that Dr. Eyrick’s education, training, and experience with the mechanical engineering of biomedical devices is extensive, and the trial court did not find otherwise.

We next turn to an analysis of the connection between Dr. Eyrick’s knowledge and the basis for his expert opinion. Dr. Eyrick testified that he disassembled an exemplar Ethicon 512SD trocar and analyzed it, thereby familiarizing himself with the engineering aspects of the trocar and how it was designed to operate. Dr. Eyrick also reviewed the remains of the Sparks trocar at issue in this case, but was unable to determine what state the trocar was in when it arrived at Ethicon for testing

because the Ethicon employee who examined and analyzed the Sparks trocar, Andres Enriquez, did so in a manner destructive to the trocar, such that it could not be reassembled. Mr. Enriquez made no visual record of his destructive testing, which occurred prior to any litigation in this case, such as videotaping or photographing the inspection. The affidavit of Dennis Thomasson, head of the engineering department and technical operations at the Ethicon plant where the Sparks trocar was returned and analyzed, attests that “[u]nfortunately, during analysis, Andres Enriquez bent or broke the knife collar, prohibiting its return to its preinspection condition.” Thus, Dr. Eyrick was unable to meaningfully examine or analyze the Sparks trocar at issue here because of Ethicon’s destructive testing of the trocar prior to litigation.

Dr. Eyrick testified that he further reviewed numerous documents provided by Ethicon regarding the 512SD trocar, including affidavit and deposition testimony of Ethicon’s experts, of Dr. Mena, who performed Ms. Sparks’s surgery, and the analysis reports documenting prior similar incidents of alleged defect or malfunction in other 512SD trocars. As the Supreme Court similarly concluded in *Brown*, we conclude that Dr. Eyrick’s testimony does not fit neatly within the *McDaniel* factors. *Brown*, 181 S.W.3d at 277. The *Brown* Court specifically noted that “[a]n expert may reach a conclusion from observations based upon his or her extensive and specialized experience,” *Id.* at 277, and that “[a]n expert may rely upon both data collected by others and tests performed by others in reaching his or her conclusions,” *Id.* at 278, both of which occurred in this case. Our review of the record persuades us that Dr. Eyrick utilized the available data, including a direct observation, disassembly, and analysis of the device at issue, to sufficiently educate himself on the mechanical engineering, design, and operation of a 512SD trocar, so that he is qualified to render an expert opinion in this case.

We acknowledge that Ms. Sparks has raised issues in addition to those addressed, but it is our determination that these additional issues are pretermitted by our decision in her favor herein.

IV. Conclusion

For the aforementioned reasons, the judgment of the trial court is vacated, and the case remanded for a new trial in accordance with this opinion. Costs on appeal are assessed to the Appellee, Ethicon Endo-Surgery, Inc.

SHARON G. LEE, JUDGE